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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	<b>Application Number</b>	09/817,725	
	<b>Filing Date</b>	March 26, 2001	
	<b>First Named Inventor</b>	Olaf B. Kinstler	
	<b>Group Art Unit</b>	1648	
	<b>Examiner Name</b>	Not Yet Assigned	
<b>Total Number of Pages in This Submission</b>		<b>Attorney Docket Number</b>	11009/35975C/US

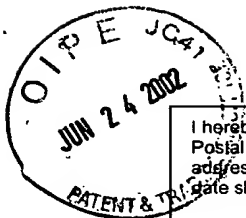
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
<b>Firm or Individual Name</b>	MARSHALL, GERSTEIN & BORUN Mark H. Hopkins, Ph.D. Reg. No. 44,775
<b>Signature</b>	
<b>Date</b>	June 19, 2002

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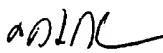
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(Mark H. Hopkins, Ph.D.)

Docket No.: 11009/35975C/US  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Olaf B. Kinstler, et al.

Application No.: 09/817725

Group Art Unit: 1648

Filed: March 26, 2001

Examiner: Not Yet Assigned

For: N-TERMINALLY CHEMICALLY  
MODIFIED PROTEIN COMPOSITIONS  
AND METHODS

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned.

A copy of each reference on PTO/SB/08 is attached with the exception of reference nos. A11, A21, A22, C24 and C26. Reference Nos. A11 and A21-22 were previously submitted in the parent case, U.S. Serial No. 08/879,760, now U.S. Patent No. 5,985,265. Reference Nos. C24 and C26 are readily available reference textbooks.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith) to our Deposit Account No. 13-2855. A duplicate copy of this paper is enclosed.

Dated: June 19, 2002

Respectfully submitted,

By 

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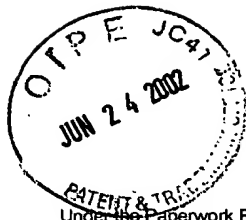
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## FOREIGN PATENT DOCUMENTS

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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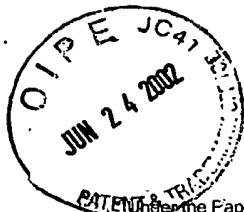
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/817725
		Filing Date	March 26, 2001
		First Named Inventor	Olaf B. Kinstler
		Group Art Unit	1648
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	11009/35975C
Sheet	3	of	4

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C20	ASANO, <i>et al.</i> "A Colorimetric Microassay for the Biological Activity of Human Granulocyte Colony-Stimulating Factor Using Murine Myeloblastic Leukemia, NSF-60 Cells," <i>Japan Pharmacol. Ther.</i> , 19:2767-2773 (1991).	
	C21	BENSINGER, <i>et al.</i> "Autologous Transplantation with Peripheral Blood Mononuclear Cells Collected After Administration of Recombinant Granulocyte Stimulating Factor," <i>Blood</i> 81(11):3158-3163 (1993).	
	C22	BODINE, D., "Mobilization of Peripheral Blood 'Stem' Cells: Where there is smoke, is there fire?", <i>Experimental Hematology</i> , 23:293-295 (1995).	
	C23	BRUGGER <i>et al.</i> , "Mobilization of Peripheral Blood Progenitor Cells by Sequential Administration of Interleukin-3 and Granulocyte-Macrophage Colony-Stimulating Factor Following Polychemotherapy with Etoposide, Ifosamide, and Cisplatin," <i>Blood</i> 79:1193-1200 (1992).	
Not encl.	C24	CRC Standard Mathematical Tables, 26 <sup>TH</sup> ed., (Beyer, W.H., Ed.) CRC Press, Inc. Boca Raton, FL 1981, p.125.	
	C25	DELGADO, <i>et al.</i> "The Uses and Properties of PEG-Linked Proteins," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 9:249-304 (1992).	
Not encl.	C26	FILGRASTIM Clinical Practice, Morstyn, G. and T.M. Dexter, Eds., Marcel Dekker Inc., New York, NY 1993, p. 351.	
	C27	GOODSON, <i>et al.</i> , "Site-directed Pegylation of Recombinant Interleukin-2 at its Glycosylation Site," <i>Bio/Technology</i> 8:343-346 (1990).	
	C28	HABEEB, A., "Determination of Free Amino Groups in Proteins by Trinitrobenzenesulfonic Acid," <i>Anal. Biochem.</i> , 14:328-336 (1966).	
	C29	HERSHFIELD <i>et al.</i> , "Treatment of Adenosine Deaminase Deficiency with Polyethylene Glycol-Modified Adenosine Deaminase," <i>N.E. Journ. of Medicine</i> , 316:589-596 (1987).	
	C30	INADA, <i>et al.</i> , "Polyethylene Glycol (PEG)-Protein Conjugates: Application to Biomedical and Biotechnological Processes," <i>J. Bioact. and Compatible Polymers</i> , 5:343-364 (1990).	
	C31	ISHIKAWA, <i>et al.</i> , "The Substitution of Cysteine 17 of Recombinant Human G-CSF with Alanine Greatly Enhanced its Stability," <i>Cell Structure and Function</i> , 17(1):61-65 (Feb. 1992)	
	C32	KATRE <i>et al.</i> , "Chemical Modification of Recombinant Interleukin 2 by Polyethylene Glycol Increases its Potency in the Murine Meth A Sarcoma Model," <i>Proc. Nat'l. Acad. Sci., USA</i> , 84:1487-1491 (1987).	
	C33	KATRE, "The Conjugation of Proteins with Polyethylene Glycol and Other Polymers," <i>Advanced Drug Delivery</i> 10:91-114 (1993).	
	C34	KODERA <i>et al.</i> "Frontier of Chemical Modification of Proteins: Application of Polyethyleneglycol-modified Enzymes in Biotechnical Processes," <i>Seikagaku</i> 60(9) 1015-1018 (1988). NO ENGLISH TRANSLATION.	
	C35	KOERHOLZ <i>et al.</i> , "Chemical and Immunological Characteristics of Four Different L-Asparaginase Preparations," <i>Eur. J. Haematol.</i> , 42 (5):417-424 (1982).	
	C36	KUGA, <i>et al.</i> , "Mutagenesis of Human Granulocyte Colony Stimulating Factor," <i>Biochem. Biophys. Res. Commun.</i> , 159(1):103-111 (1989).	
	C37	LAEMMLI, "Cleavage of Structural Proteins During the Assembly of the Head of Bacteriophage T4," <i>Nature</i> , 227:680-685 (1970).	
	C38	LU, <i>et al.</i> , "Disulfide and Secondary Structures and Recombinant Human Granulocyte Colony Stimulating Factor," <i>Arch. Biochem. Biophys.</i> , 268:81-92 (1989).	
	C39	METCALF, "The Molecular Biology and Functions of the Granulocyte-Macrophage Colony-Stimulating Factors," <i>Blood</i> , 67: 257-267 (1986).	

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				Application Number	09/817725
				Filing Date	March 26, 2001
				First Named Inventor	Olaf B. Kinstler
				Group Art Unit	1648
				Examiner Name	Not Yet Assigned
Sheet	4	of	4	Attorney Docket Number	11009/35975C

C40	MORSTYN, "Effect of Granulocyte Colony Stimulating Factor on Neutropenia Induced by Cytotoxic Chemotherapy," <i>The Lancet</i> , 667-674 (1998).	
C41	NEBEN, <i>et al.</i> , "Mobilization of Hematopoietic Stem and Progenitor Cell Subpopulations from the Marrow to the Blood of Mice Following Cyclophosphamide and/or Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 81(7):1960-1967 (1993).	
C42	NIVEN, <i>et al.</i> , "Pulmonary Absorption of Polyethylene Glycolated Recombinant Human Granulocyte-Colony Stimulating Factor (PEG rhG-CSF)," <i>J. Controlled Release</i> , 32:177-189 (1994).	
C43	OKABE, <i>et al.</i> , " <i>In Vitro</i> and <i>In Vivo</i> Hematopoietic Effect of Mutant Human Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 75(9):1788-1793 (May, 1990).	
C44	ORLIC, <i>et al.</i> , "Mobilized Bone Marrow Cells Repair the Infarcted Heart, Improving Function and Survival," <i>Proc. Natl. Acad. Sci. USA</i> 18:10344-10349 (2001).	
C45	RALPH, <i>et al.</i> , "Inducible Production of Human Macrophage Growth Factor, CSF-1," <i>Blood</i> , 66: 633-639 (1988).	
C46	ROBERTS, <i>et al.</i> , "Granulocyte Colony-Stimulating Factor Induces Selective Elevations of Progenitor Cells in the Peripheral Blood of Mice," <i>Expt'l. Hematology</i> , 22: 1156-1163 (1994).	
C47	SATAKE-ISHIKAWA, <i>et al.</i> , "Chemical Modification of Recombinant Human Granulocyte Colony-Stimulating Factor by Polyethylene Glycol Increases its Biological Activity <i>In Vivo</i> ," <i>Cell Structure and Function</i> , 17:157-160 (1992).	
C48	SCHAPER, W., "Therapeutic Arteriogenesis Has Arrived," <i>Circulation</i> , 104: 1994-1995 (2001).	
C49	SEILER, <i>et al.</i> , "Promotion of Collateral Growth by Granulocyte-macrophage Colony-Stimulating Factor in Patients with Coronary Artery Disease, A Randomized, Double-Blind, Placebo-Controlled Study," <i>Circulation</i> , 104:2012-2017 (2001).	
C50	STOCKS, <i>et al.</i> , "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol," <i>Anal. Biochem.</i> , 154:232-234 (1986).	
C51	SUSSMANN, M. "Hearts and Bones," <i>Nature</i> , 410:640-641 (2001).	
C52	WELTE, <i>et al.</i> , "Purification and Biochemical Characterization of Human Pluripotent Hematopoietic Colony-Stimulating Factor," <i>Proc. Nat'l Acad. Sci (USA)</i> 82:1526-1530 (1985).	
C53	YAMASAKI, <i>et al.</i> , "Modification of recombinant Human Granulocyte Colony-Stimulating Factor (rhG-CSF) and Its Derivative ND 28 with Polyethylene Glycol," <i>Biochem.</i> , 115:814-819 (1994).	
C54	YAN, <i>et al.</i> , "Mobilization of Long-Term Hematopoietic Reconstituting Cells in Mice by the Combination of Stem Cell Factor Plus Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 84(3):795-799 (1994).	

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